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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,073	01/08/2004	Jacques Paris	04000CIP	5432

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/753,073	PARIS ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 23 June 2005.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10,12-27 and 29-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10,12-27 and 29-33 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/284,147, 09/423,108

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading.

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT
(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(f) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(g) BRIEF SUMMARY OF THE INVENTION.
(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(i) DETAILED DESCRIPTION OF THE INVENTION.
(j) CLAIM OR CLAIMS (commencing on a separate sheet).
(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Examiner notes that if one or more of the sections above are not applicable it is not necessary to insert the section heading in the Specification.

The disclosure is objected to because of the following informalities: It appears that disclosures from two separate application where simply attached together, as such, the

Specification refers to different examples and tables by the same Roman numerals and has what appears to be additional background material and summary of invention material in the middle of the Specification. Further, the first page of the Specification is missing the title.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10, 33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the end point of administration of the pharmaceutical composition containing the steroids, i.e. 25 or 28 days. The Specification only discloses administration for 21-25 or 21-28 days. (Specification, pg. 4, line 6, pg. 21, lines 22-26). Further, with respect to claim 33, if the embodiment of the claimed invention contains 28 pills there cannot be a placebo pill since the period of administration is disclosed as being from 21-28 days (Specification, pg. 21, lines 22-26). Examiner suggests for claim 1 that Applicant replace "for at least 21 days" with "for 21 days to 25 days" and canceling claim 12. With respect to claim 33, Examiner suggests the following limitation "with the proviso that for the contraceptive product comprising 28 of said dosage forms that said product does not further comprise a dosage form comprising a placebo".

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10, 12-27, 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jamin, Rev. fr. Gynécol.Obstét (1992), Vol. 87, No. 6, pp. 370-376 in view of Powers et al. (Abstract), Bazin et al. (Abstract), Paris et al.(Abstract) and Hodgen (US Pat. 5,552,394).

Jamin discloses a combination of 5 mg/day of nomegestrol acetate and transdermal estradiol at 50 mcg/day. Eighteen (18) women aged 19-40 who had experience menstrual problems with high dose of progestins. Period of use ranged from 3 months to 3 years and total 272 cycles of 20 days/28. No pregnancies occurred and cycle control was good, and clinical tolerance was excellent. Jamin also discloses that there has been a long history of use of oral contraceptives. See entire document, especially Abstract and pgs. 370-372, 375.

Powers et al. discloses that transdermal estradiol at 0.025, 0.05 or 0.1 mg/day is comparable to oral dosages of estradiol of 2 mg and 1.25 mg of conjugated equine estrogens (Abstract).

Bazin et al. disclose that doses of 1.25, 2.5 and 5 mg a day was effective in inhibiting ovulation (Abstract).

Paris et al. disclose that nomegestrol has no side effects such as androgenic activity (Abstract).

Hodgen discloses the combination of estrogen and progestin for 23-25 consecutive days of a 28 day cycle, preferably 24 days using tables containing both the estrogen and progestin and then for 4 days with placebo which is disclosed to be effective for contraception (Column 3, lines 50-61, Column 3, lines 44-50). It is disclosed that useable estrogens include esters of estradiol, such as valerate, and conjugated equine estrogens (Column 4, lines 13-16).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of nomegesterol and estradiol in a single composition. However, the prior art amply suggests the prior art discloses that oral contraceptives and use of the same are well known and that nomgesterol and estradiol can be used as co-therapy as contraceptives. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to combine nongesterol and estradiol in a single oral dose for purposes of convenience, i.e the patient would only have to remember to take a single dosage form a day as opposed to having to remember to self-administer two dosage forms and would be motivated to vary doses and periods of administration depending on effectiveness in reducing the risk of pregnancy. Further, one of ordinary skill in the art would expect that any pharmaceutically acceptable form of estradiol could be used with the expectation that the combination of the same with nongesterol would be effective in contraception.

Examiner has duly considered Applicant's arguments and declaration but deems them unpersuasive.

Applicant argues that the amounts of nomegestrol acetate claimed is not the same as the amount of nomegestrol disclosed. However, with respect to claims 1 and 13, the amount disclosed is "about 3.75 mg". Applicant has not shown that the term "about" excludes 5 mg.

With respect to claims 17 and 29, it would have been well within the skill of one of ordinary skill in the art to vary the amount of nomegestrol depending on contraceptive effectiveness including to amounts falling within the scope of 0.1 to 2.5 mg. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 191 USPQ 90 (CCPA 1976); In re Woodruff, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of "about 1-5%" while the claim was limited to "more than 5%." The court held that "about 1-5%" allowed for concentrations slightly above 5% thus the ranges overlapped.); In re Geisler, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of "50 to 100 Angstroms" considered prima facie obvious in view of prior art reference teaching that "for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms]." The court stated that "by stating that suitable protection' is provided if the protective layer is about' 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant's] claimed range."). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105

USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be prima facie obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%.); see also Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003)("The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.").

Applicant argues that it is unexpected that the combination of the claimed estrogen with nomegestrol acetate in the claimed amounts exhibits potentiated activity. However, it is well known in the art to combine progestin and estrogen in order to reduce side effects and break-through bleeding (Hodgen at Column 2, lines 1-10). Further, one of ordinary skill in the art would have been motivated to select nomegestrol as it has no side effects such as androgenic activity (Paris et al. (1983), Abstract). The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 173 USPQ 560 (CCPA 1972); In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991).

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1-10, 12, 17-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over FR 2754179 (published 4/10/1998) in view of Hodgen et al. (US Pat. 5,552,394).

FR 2754179 discloses the combination of 1.5 to 3.75 mg or 2.5 mgs of nomegestrol acetate with 0.5 to 3 mg of estradiol, or 1.5 mg of estradiol, 2mg of an ester of estradiol or 0.625 mg of conjugated equine estrogens in the form of oral dosage form, such as tablets, for contraception (Page 3, lines 20-32, Page 4, lines 3-26).

Hodgen et al. is cited for the same reasons as above and is incorporated herein to avoid repetition.

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose methods for contraception and products containing at least 21 days of the combination of an oral dosage of estradiol, ester of estradiol or conjugated equine estrogen and nomegestrol acetate in the amounts claimed. However, the prior art amply suggests the same as the prior art discloses oral dosages forms containing containing 21-25 days of the combination of an oral dosage of estradiol, ester of estradiol or conjugated equine estrogen and nomegestrol acetate in the amounts claimed used as a contraceptive, the use of estradiol valerate, and the use of placebos after 25 days of consecutive treatment of the combination of estrogen and progestin. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination of said estrogen and said progestin would be effective as a contraceptive.

A claim complies with 35 USC Section 120 and acquires an earlier filing date, if and only if it could have been added to an earlier application without introducing new matter. See Studiengesellschaft Kohl, m.b.h. v. Shell Oil, 42 USPQ2d 1674, 1677 (Fed. Cir. 1997). Further, the disclosures of two earlier filed applications cannot be combined to acquire an earlier filing date under 35 USC Section 120. *Id.* Furthermore, notwithstanding that an embodiment may be

obvious from the disclosure, this is insufficient to satisfy the written description requirement. See In re Ruschig, 154 USPQ 118, 123 (CCPA 1967) ("If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it").

With respect to claims 1-10, 12, said claims are only entitled to a priority date of 1/8/2004 as it does not appear that a single priority document discloses all limitations of claim 1. The line of cases represented by Application 09/423,108, having an effective priority date of 10/25/1999, recites a range of 21-28 days and 21-28 dosage forms and administering on the 1st day of the cycle, however, the limitation "at least 21 days" includes days outside the range of 21-28 days. The line of cases represented by Application 09/284,147, having an effective filing date of 10/8/1996, recites a range of 21-25 days in which the oral contraceptives are administered, however the limitation of "at least 21 days" includes days outside the range of 21-25 days and there is no written description of the limitation "from the first day of her cycle". With respect to claims 17-27, 29-33, said claims are only entitled to a priority date of 10/25/1999 as it appears that only the line of cases represented by 09/423,108. The line of cases represented by Application 09/284,147, having an effective filing date of 10/8/1996, recites a range of 21-25 days, however the limitation of "for 21 days to 28 days" and "21 to 28 dosage forms" includes days and doses outside the range of 21-25 days in which the oral contraceptives are administered and there is no written description of the limitation "from the first day of her cycle".

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Terminal Disclaimer

The terminal disclaimer filed on 6/23/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. 6909049 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
September 11, 2005

JOHN PAK
PRIMARY EXAMINER
GROUP 1600